

## **A new smart neonatal incubator for real-time detection of sepsis**

Award Information

Agency:

Department of Health and Human Services

Branch

n/a

Amount:

\$494,686.00

Award Year:

2012

Program:

SBIR

Phase:

Phase I

Contract:

1R43HD072926-01

Agency Tracking Number:

R43HD072926

Solicitation Year:

2012

Solicitation Topic Code:

NICHD

Solicitation Number:

HD12-192

Small Business Information

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Hubzone Owned:

N

Socially and Economically Disadvantaged:

N

Woman Owned:

N

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#### Abstract

**DESCRIPTION** (provided by applicant): Isomark LLC has developed a breath-based early detection technology (comprised of biomarkers and instruments for detection) that can pinpoint the onset of acute systemic inflammation. Isomark's breath biomarkers may provide an indicator of neonatal health. This technology will 1) improve neonatal care outcomes and save lives, and 2) reduce costs associated with excessive management of the neonatal intensive care unit (NICU) patient by reducing infections, thus leading to shorter hospital stays - a major source of expense in neonatal care. Isomark's goal for this project is to provide a new 'smart' neonatal incubator product for real-time assessment of neonatal health in the NICU. **The Problem:** More than 90% of infants undergo unnecessary treatment during sepsis evaluations in cases of chorioamnionitis due to a lack of an early and specific marker for infection. Chorioamnionitis is an inflammatory response of the chorioamnion due to infection. Chorioamnionitis is a leading cause of prelabor preterm rupture of membranes (PPROM) and a leading cause of premature birth (lt 35 weeks). Although only about 3 to 10% of neonates develop congenital sepsis in confirmed cases of chorioamnionitis, prophylactic antibiotic treatment is initiated as a precautionary measure. Prophylactic antibiotic treatment continues for up to 72 hours while infants are evaluated and cultures are allowed to grow in order to confirm the presence or absence of infection. The infant is frequently separated from the mother while in the NICU for antibiotic treatment. Thus up to three days of unnecessary treatment occurs in up to 97% of cases, at a significant cost to the health care system. **Isomark's technology:** Isomark has developed a non-invasive and easily identifiable biomarker for real-time monitoring of patients suspected of having systemic inflammation or infection. In preclinical studies, Isomark's technology effectively detected the onset of infection via breath delta values (i.e.  $13C/12C$  ratio) as early as 2 hours after onset of induced endotoxemia and 14 to 18 hours earlier than clinical signs of septic shock. The breath delta value successfully discriminated systemic inflammatory response syndrome (SIRS) from no-SIRS in preliminary clinical data from mechanically ventilated pediatric patients. Based on these preclinical data, we believe that Isomark's noninvasive breath analysis will provide neonatal clinicians with a new means of screening patients for acute systemic inflammation and potential infections. This new tool can be used to screen neonates with chorioamnionitis to eliminate the need for unnecessary antibiotic treatment and NICU stays. **Isomark's Team:** In phase I, a team consisting of Isomark staff, University of Wisconsin's Neonatal researchers and GE Global Research engineers will address technical aspects of non-invasive breath biomarker measurements in infants in critical care incubators, and determine the carbon delta value for detecting acute inflammation/infection in neonates born to mothers with chorioamnionitis. **Proposed Product:** The successful completion of this project will result in a new 'smart' neonatal incubator capable of real-time detection of acute systemic inflammation. The Phase I project will generate convincing data that demonstrate changes in breath delta value are a biomarker for acute systemic inflammation in neonates. In phase II, we will equip neonatal incubators with Isomark's real-time breath detection system and will field deploy these incubators to demonstrate effective segregation of acute systemic inflammation in neonates. In phase III, Isomark will perform clinical trials for FDA clearance of the new incubator for early detection of sepsis, and then begin marketing the device. **PUBLIC HEALTH RELEVANCE:** The relevance of this project will lead to earlier detection of critical inflammatory illnesses, such as systemic inflammation and sepsis, in at risk infants. **Public Health:** Products developed in this project will lead to reduced need for unnecessary treatment, treatment of illnesses before they become critical, and a reduction of lifelong consequences of critical illness in premature infants.

\* information listed above is at the time of submission.